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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,675	01/29/2004	Tom McHale	S63.2-10813US01	5432

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VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
09/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,675	MCHALE ET AL.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07 August 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites the limitations "the recessed portion" and "the balloon distal cone portion" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 5, 6, 12-14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Samson et al. (4,597,755).** Samson et al. (hereinafter Samson) reference discloses the catheter substantially as claimed (see patent).

6. Regarding claim 1, Samson discloses a catheter shaft (12), an inflation balloon (37), and a catheter tip (21). The balloon has proximal and distal waist portions (the portions where the balloon is engaged to the tubes 36 and 21), proximal and distal cone portions (the angled portions of the balloon), and a main body portion (the widest portion of the balloon). The catheter tip has a main shaft portion (that which underlies the balloon) and a distal shaft portion (that which extends from the balloon, see figure 2). The proximal end of the tip is coupled to the distal end (14) of the catheter shaft (see figure 2). The catheter tip also has a recessed portion (see annotated figure below) that extends under the balloon, and in particular under a portion of the distal cone section of the balloon. The portions labeled recessed below are all recessed radially inward *relative* to the outermost surface of the catheter shaft (at 21). In the unexpanded configuration, the balloon will rest in those recessed portions.

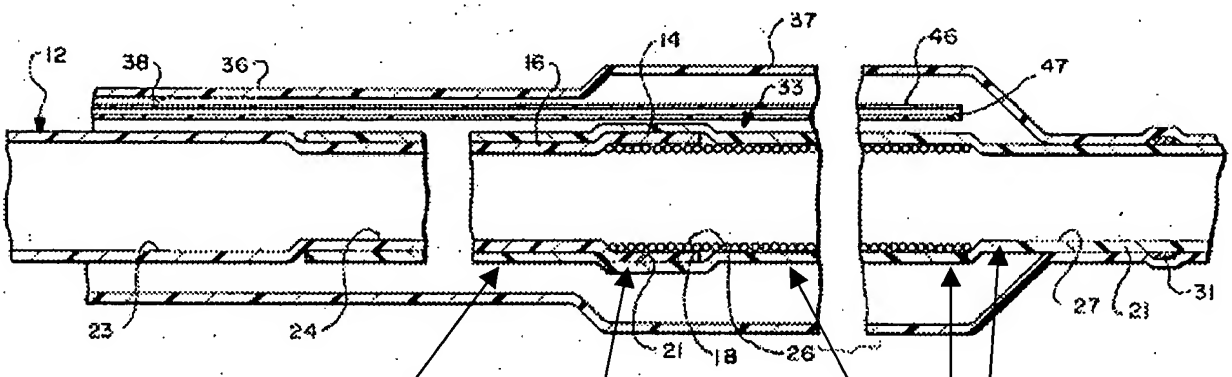

FIG.—2

Recessed Portion

Outermost Surface

Recessed Portions

7. Regarding claim 5, the distal end of the tip has a radius because it is circular.

8. Regarding claim 6, the tip further has a second recessed portion (as shown above). The second recessed portion is under the proximal cone section of the balloon.

9. Regarding claims 12 and 13, the catheter further includes a spring stiffener (18).

10. Regarding claim 14, the catheter includes a marker (31, see figure 2).

11. Regarding claim 17, the catheter further includes an outer catheter shaft (36) that has the proximal end of the balloon coupled thereto (see figure 2).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Millar (4,665,925).** Samson reference does not disclose a marker disposed beneath the balloon main body portion. Attention is drawn to Millar reference, which teaches radiopaque markers (58) disposed under the balloon main body portion (see figure 2) to allow for proper placement of the balloon at an operative site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place radiopaque markers under the balloon main body portion of Samson reference, as taught by Millar, to allow for proper placement of the balloon at an operative site.

14. Regarding claim 4, MRI and radiopaque markers are art recognized equivalents.

15. **Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Ellis et al. (6,395,008).** Samson reference does not disclose a hub portion on the catheter. Attention is drawn to Ellis et al. (hereinafter Ellis) reference, which teaches a hub portion (74) may be formed on a catheter tip to help create a tighter connection between the balloon and the shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a hub with the tip, as taught by Ellis reference, to help create a tighter connection between the balloon and the shaft.

16. Regarding claim 8, the hub portion is shown integrally formed with the tip section (see the dotted lines in figure 8).

17. Regarding claim 9, Samson reference discloses a marker (31, see figure 2).

18. **Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) in view of Ellis et al. (6,395,008) as applied to claim 9 above, and further in view of Follmer et al. (5,728,065).** The combination of Samson and Ellis references does not disclose the marker is flush with the outer surface of the tip. Attention is drawn to Follmer et al. (hereinafter Follmer) reference, which teaches a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a lower profile because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert mold flush the marker of Samson in view of Ellis with the tip, as taught by Follmer reference, to create a tip that has a lower profile.

19. **Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Follmer et al. (5,728,065).** Samson reference does not disclose the catheter tip has a first and second region wherein the first region has greater flexibility than the second region. Attention is drawn to Follmer reference, which teaches a catheter tip may have two regions (122 and 114) with the second region (114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of Samson reference of two regions wherein the first region is more flexible than the second region, as taught by Follmer reference, to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

20. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) in view of Follmer et al. (5,728,065) and further in view of Chee et al. (5,906,606).** Samson reference discloses a catheter shaft (12), an inflation balloon (37), and a catheter tip (21) having a recessed portion (see annotated figure above with respect to claim 1) that extends under the balloon, and in particular under a portion of the distal cone section of the balloon. The portions labeled recessed below are all recessed radially inward *relative* to the outermost surface of the catheter shaft (at 21). In the unexpanded configuration, the balloon will rest in those recessed portions.

The balloon has proximal and distal waist portions (the portions where the balloon is engaged to the tubes 36 and 21). The catheter tip has a main shaft portion (that which underlies the balloon) and a distal shaft portion (that which extends from the balloon, see figure 2). The proximal end of the tip is coupled to the distal end (14) of the catheter shaft (see figure 2). However, Samson reference does not disclose the catheter tip has a first and second region wherein the first region has greater flexibility than the second region. Attention is drawn to Follmer reference, which teaches a catheter tip may have two regions (122 and 114) with the second region (114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of Samson reference of two regions wherein the first region is more flexible than the second region, as taught by Follmer reference, to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

21. Further regarding claim 16, the combination of Samson and Follmer references does not disclose the second region comprises stiffeners that are carbon fibers. Attention is drawn to Chee et al. (hereinafter Chee) reference, which teaches a catheter tip may be reinforced with carbon fibers (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon

fibers of Chee to replace the ribbons of Follmer as the reinforcements in the second region to create a device that has the rigidity desired in the second region but reduces the weight of the device by using the carbon fibers instead of larger ribbons.

22. **Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Gambale et al. (6,447,522).** Samson reference does not disclose the catheter tip is coupled to the catheter shaft by heat bonding. Attention is drawn to Gambale et al. (hereinafter Gambale) reference, which teaches two shafts may be coupled by heat bonding (see column 7, lines 12-18) to maintain a secure connection there between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple the catheter tip to the catheter shaft using heat bonding, as taught by Gambale reference, to maintain a secure connection there between.

23. **Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Cathcart et al. (5,951,585).** Samson reference does not disclose the catheter tip is coupled to the catheter shaft by radio-frequency (RF) welding or using adhesive. Attention is drawn to Cathcart et al. (hereinafter Cathcart) reference, which teaches either RF welding or the use of adhesives to join a shaft to another tubular member (see column 8, lines 47-49) to maintain a secure connection there between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple the catheter tip to the catheter shaft using either RF welding or

adhesives, as taught by Cathcart reference, to maintain a secure connection there between.

24. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Imran et al. (5,766,203).** Samson reference does not disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al. (hereinafter Imran) reference, which teaches a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of Samson reference as a stent delivery catheter, as taught by Imran reference, to deliver a stent to provide permanent support to a weakened vessel.

25. Regarding claim 22, Imran et al. reference discloses a stent mounted about the balloon (see figure 8C).

26. Regarding claim 23, the stent of Imran is an inflation expandable stent (see column 8, lines 36-41).

27. Regarding claim 24, the Imran stent can be self-expanding (column 8, line 56).

28. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (4,597,755) as applied to claim 1 above, and further in view of Hamilton et al. (6,514,228).** Samson reference does not disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton et al. (hereinafter Hamilton) reference, which teaches an inner catheter tip may have a triangular cross section (see figure 9C) to allow a greater amount of balloon inflation fluid to be dispensed into the

balloon (see column 7, lines 31-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the catheter tip of Samson in a triangular shape, as taught by Hamilton reference, to allow a greater amount of balloon inflation fluid to be dispensed into the balloon.

Response to Arguments

29. Applicant's arguments filed 07 August 2007 have been fully considered but they are not persuasive. Applicant argues that Samson does not disclose the balloon rests in the recessed portion. Examiner disagrees, for the reasons set forth with respect to claim 1 above.

Conclusion

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571) 272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.S.

Ryan Severson
September 25, 2007

LOAN H. THANH
PRIMARY EXAMINER